UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
Civil No. 14-4739(DSD/HB)

Wayne Wenzel,

Plaintiff,

v. **ORDER**

Blue Cross Blue Shield of Minnesota and Syngenta Crop Protection, LLC Preferred Provider Organization (PPO) Health Care Plan,

Defendant.

Katherine L. MacKinnon, Esq., Sarah J. Demers, Esq. and Law Office of Katherine L. MacKinnon, 3744 Huntington Avenue, St. Louis Park, Minneapolis 55416, counsel for plaintiff.

Doreen A. Mohs, Esq., and Blue Cross and Blue Shield of Minnesota, P.O. Box 64569, M4-95, Eagan, Minnesota 55164 and Joel A. Mintzer, Esq. and Blue Cross and Blue Shield of Minnesota, P.O. Box 64560, St. Paul, Minnesota, counsel for defendant.

This matter is before the court upon the cross-motions for summary judgment by plaintiff Wayne Wenzel and defendants Blue Cross Blue Shield of Minnesota and Syngenta Crop Protection, LLC Preferred Provider Organization (PPO) Health Care Plan (the Plan). Based on a review of the file, record, and proceedings herein, and for the following reasons, the court denies plaintiff's motion and grants defendants' motion.

BACKGROUND

This insurance benefit dispute arises out of Blue Cross' denial of medical coverage for Wenzel under the Plan. Wenzel's Plan provides him the right to "receive quality health care" and "benefits for covered services." Admin. R. at 13, 18. Blue Cross is the claims administrator for the Plan. Id. at 18. Relevant to this dispute, the Plan does not cover "[c]harges for or related to care that is investigative." Id. at 72.

In 2007, Wenzel was diagnosed with relapsing/remitting multiple sclerosis (MS). Id. at 352. In 2013, Wenzel's condition worsened and he suffered two relapses. Id. at 352, 356, 383-85. Wenzel met with Dr. Richard Burt of Northwestern Memorial Hospital (NMH), who determined that Wenzel was a good candidate for a medical procedure known as autologous stem-cell transplantation (ASCT). Id. at 353, 358. It is undisputed that ASCT was not and still is not approved for FDA marketing. ASCT is currently in phase III clinical trials. Id. at 343, 559. Dr. Burt invited Wenzel to participate in a clinical trial for ASCT. Compl. ¶ 20; Admin. R. 444-49. Dr. Burt said that he would treat Wenzel "on a compassionate basis," which guaranteed that Wenzel would receive treatment and removed the possibility that he would be placed in the untreated control group. Compl. ¶ 20.

In anticipation of the procedure, NMH submitted a request for prior approval of coverage under the Plan to Blue Cross. Admin. R.

at 341-434. In its request, NMH touted its past success with ASCT and stated that Wenzel would likely benefit from the procedure. Id. at 343. Blue Cross examined whether or not ASCT for MS was "investigative" and should be excluded from coverage. Id. at 337-39, 441-43. The Plan's full definition of "investigative" is as follows:

> A drug, device, diagnostic procedure, technology, or medical treatment or procedure is investigative if reliable evidence does not permit conclusions concerning its safety, effectiveness, or effect on health outcomes. The Claims Administrator bases its decision upon an examination of the following reliable evidence, none of which is determinative in and of itself:
>
> 1. the drug or device cannot be lawfully marketed without approval of the U.S. Food and Drug Administration and approval for marketing has not been given at the time the drug or device is furnished;
>
> 2. the drug, device, diagnostic procedure, technology, or medical treatment or procedure is the subject of ongoing phase I, II, or III clinical trials (Phase I clinical trials determine the safe dosages of medication for Phase II trials and define acute effects on normal tissue. Phase II clinical trials determine clinical response in a defined patient setting. If significant activity is observed in any disease during Phase II, further clinical trials usually study a comparison of the experimental treatment with the standard treatment in Phase III trials. Phase III trials are typically quite large and require many patients to determine if a treatment improves outcomes in a large population of patients);

> 3. medically reasonable conclusions establishing its safety, effectiveness, or effect on health outcomes have not been established. For purposes of this subparagraph, a drug, device, diagnostic procedure, technology, or medical treatment or procedure shall not be considered investigative if reliable evidence shows that it is safe and effective for the treatment of a particular patient.
>
> Reliable evidence shall also mean consensus opinions and recommendations reported in the relevant medical and scientific literature, peer-reviewed journals, reports of clinical trial committees, or technology assessment bodies, and professional expert consensus opinions of local and national health care providers.

Id. at 105. The Plan delegates to Blue Cross' Medical Policy Committee (MPC) the task of determining whether a procedure is investigative or should be a covered benefit:

> The Claims Administrator's Medical Policy Committee determines whether new or existing medical treatment should be covered benefits. The Committee is made up of independent community physicians who represent a variety of medical specialties. The Committee's goal is to find the right balance between making improved treatments available and guarding against unsafe or unproven approaches. The Committee carefully examines the scientific evidence and outcomes for each treatment being considered.

Id. at 30.

In 2009, the MPC created a policy study entitled "Hematopoietic Stem-Cell Transplantation for Autoimmune Diseases" and referred to as the "Medical Policy Manual II-121" (MPM II-121). Id. at 747, 749. The MPM II-121 was developed for use by Blue

Cross' claims reviewers. Id. at 747. The policy study summarizes peer-reviewed medical literature and analyzes whether ASCT should be considered "investigative." Id. at 747–58. The MPM II-121 ultimately concluded that ASCT was investigative under the Plan when used to treat MS. Id. That conclusion was approved by the MPC and has been reviewed and approved annually since its inception. Id. at 117.

Blue Cross referred Wenzel's request for coverage to a medical director. Id. at 441-43. The medical director reviewed Wenzel's medical records and other documents that he submitted to Blue Cross. Id. The medical director also reviewed relevant medical literature and the MPM II-121. Id. Ultimately, the medical director concluded that the procedure met the Plan's definition of "investigative" and therefore was ineligible for coverage. Id. at 441-43. Accordingly, Blue Cross denied NMH's request for the Plan to cover Wenzel's ASCT procedure. Id. at 337–39.

Wenzel twice appealed Blue Cross' denial of the request to cover the ASCT procedure. Id. at 759-875, 151-228. He was denied at each stage. Id. at 247-49, 127-29. With each denial, Wenzel had the right "to receive copies of the actual benefit provision, guideline, protocol, or other similar criteria or documents upon which th[e] decision was made, free of charge." Id. at 128, 249, 338. However, Wenzel never asked to look into the details of Blue Cross' decision-making process.

Blue Cross also sent Wenzel's appeals files to an independent external medical reviewer, Advanced Medical Reviews (AMR). Id. at 547-557. AMR affirmed the decision to deny coverage to Wenzel and, in doing so, examined the Plan's definition of "investigative." Id. at 558-60. In addition to reviewing the files submitted by Wenzel and Blue Cross, AMR cited a 2011 systematic review of ASCT procedures and the results of numerous other studies. Id. at 559-60. AMR concluded that "further studies are still needed to determine whether the use of [ASCT] would improve overall health outcomes in patients with [MS] when compared to standard treatment options." Id. at 560.

Wenzel elected to pay out-of-pocket for the cost of the ASCT procedure. Compl. ¶ 28. He was hospitalized at NMH from January 16, 2014, to February 1, 2014, for the procedure. Id. Wenzel's total out-of-pocket costs for the ASCT procedure were $166,138.94. Id. ¶ 30, Ex. 5.

On November 12, 2014, Wenzel filed a complaint alleging that he was entitled to coverage and seeking reimbursement for the benefits denied to him under the Plan. The parties now bring cross-motions for summary judgment.

DISCUSSION

I. Standards of Review

1. Summary Judgment

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); see Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). A fact is material only when its resolution affects the outcome of the case. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A dispute is genuine if the evidence is such that it could cause a reasonable jury to return a verdict for either party. Id. at 252.

On a motion for summary judgment, the court views all evidence and inferences in a light most favorable to the nonmoving party. Id. at 255. The nonmoving party, however, may not rest upon mere denials or allegations in the pleadings but must set forth specific facts sufficient to raise a genuine issue for trial. Celotex, 477 U.S. at 324. A party asserting that a genuine dispute exists - or cannot exist - about a material fact must cite "particular parts of materials in the record." Fed R. Civ. P. 56(c)(1)(A). If a plaintiff cannot support each essential element of a claim, the court must grant summary judgment because a complete failure of proof regarding an essential element necessarily renders all other facts immaterial. Celotex, 477 U.S. at 322-23.

2. ERISA Benefit Decision

If a plan administrator has discretionary authority to determine eligibility, the court generally reviews an administrator's decision for an abuse of discretion. Firestone Tire & Rubber Co. v. Bruch, 489 U.S. 101, 111-15 (1989). Under this standard, an "administrator's interpretation of uncertain terms in a plan will not be disturbed if reasonable" and supported by "substantial evidence." King v. Hartford Life & Acc. Ins. Co., 414 F.3d 994, 999 (8th Cir. 2005) (en banc) (citation and internal quotation marks omitted). The Eighth Circuit employs a balancing test to determine the reasonableness of an administrator's interpretation. Finley v. Special Agents Mut. Benefit Ass'n, Inc., 957 F.2d 617, 621 (8th Cir. 1992). This test sets forth several factors for a court to consider, including whether an administrator's interpretation: (1) is consistent with the goals of the Plan; (2) renders any language of the Plan meaningless or internally inconsistent; (3) conflicts with the requirements of ERISA; (4) has been applied consistently; and (5) is contrary to the clear language of the Plan. Finley, 957 F.2d at 621.

The parties do not dispute that Blue Cross, as the plan administrator, had discretionary authority to determine eligibility. Thus, the court reviews Blue Cross' denial for abuse of discretion.

II. Blue Cross' Basis for Denial of Coverage

The court must affirm a plan administrator's decision "if a reasonable person could have reached a similar decision, given the evidence before him, not [because] a reasonable person would have reached that decision." Rutledge v. Liberty Life Assur. Co. of Boston, 481 F.3d 655, 659 (8th Cir. 2007) (emphasis in original) (citation and internal quotation marks omitted). To be reasonable, a decision must be based on substantial evidence. Wise v. Kind & Knox Gelatin, Inc., 429 F.3d 1188, 1190 (8th Cir. 2005). "Substantial evidence" is not a mere scintilla, but rather what a reasonable person might accept as adequate to support the decision. Norris v. Citibank, N.A. Disability Plan (501), 308 F.3d 880, 884 (8th Cir. 2002).

1. Reasonableness of "Investigative" Classification for ASCT Specific to Wenzel

Wenzel argues that Blue Cross abused its discretion because it ignored his assertion that ASCT was safe and effective for his particular situation. Specifically, Wenzel argues that Blue Cross ignored the details of his case and the language of the Plan, and instead blindly followed the MPM II-121. To support his argument, Wenzel asserts that Blue Cross ignored a sentence in the third subparagraph in the Plan's definition of "investigative," which states, "For purposes of this subparagraph, a drug, device, diagnostic procedure, technology, or medical treatment or procedure shall not be considered investigative if reliable evidence shows

that it is safe and effective for the treatment of a particular patient." Admin. R. at 105.

A "plan administrator's decision need not be the only sensible interpretation" and "should not be disturbed even if another reasonable, but different interpretation may be made." Tillery v. Hoffman Enclosures, Inc., 280 F.3d 1192, 1199 (8th Cir. 2002). Plan administrators are not required to "automatically accord special weight to the opinions of a claimant's physician." Black & Decker Disability Plan v. Nord, 538 U.S. 822, 829-31 (2003); see also McGee v. Reliance Standard Life Ins. Co., 360 F.3d 921, 925 (8th Cir. 2004) (holding that a plan administrator is "not obligated to accord special deference to the opinion of ... the treating physician, over the conflicting opinion of ... the reviewing physician"). Nor are plan administrators required to explain a decision to "credit reliable evidence that conflicts with a treating physician's evaluation." Black & Decker Disability Plan, 538 U.S. at 829-31.

The medical director for Blue Cross reviewed Dr. Burt's letter, which opined that Wenzel was a prime candidate for the ASCT procedure. Admin. R. at 342-43, 441-42. Dr. Burt sent Blue Cross ninety-four pages of materials specifically regarding Wenzel's situation. Id. at 341-434. The medical director specifically reviewed Wenzel's "[m]edical records" and his "case summary." Id. at 442.

The medical director also reviewed the MPM II-121. Id. at 441-42. The draft discussion for the MPM II-121 actually cites two of Dr. Burt's published studies and discusses his research. Id. at 755-58. The MPM II-121 goes on to note that "[s]everal editorials" agreed that the role of ASCT "is not established in MS." Id. at 756. The MPM II-121 also notes that ASCT is still in clinical trials, and that "follow-up is needed before conclusions can be reached from study findings." Id. at 757. In total, the MPM II-121 cites eleven peer-reviewed papers on ASCT. Id. at 758. Overall, the MPM II-121 reasonably explains why ASCT is too underdeveloped to be considered non-investigative for any patient.

Dr. Burt's own treatment of Wenzel belies the claim that ASCT is conclusively non-investigative. Dr. Burt agreed to provide the treatment "on a compassionate basis." Compl. ¶ 20. The FDA states that such "compassionate" care "provides a pathway for patients to gain access to investigational drugs ... [which] have not yet been approved by the FDA and ... have not been proven to be safe and effective." Food & Drug Admin., http://www.fda.gov/forpatients/other/expandedaccess/default.htm (last visited Oct. 26, 2015); see also 21 C.F.R. § 312.300 (discussing "the requirements for the use of investigational new drugs"). Dr. Burt's own treatment of Wenzel under the umbrella of "compassionate" care confirms ASCT's investigative nature.

Finally, the Plan specifically notes that no single factor discussed in the definition of "investigative" is determinative in and of itself. Wenzel points to one sentence, regarding whether "reliable evidence shows that [treatment] is safe and effective for the treatment of a particular patient." Admin. R. at 105. Yet the Plan limits the scope of this sentence to one of the factors of the definition. Moreover, the two other delineated factors clearly indicate ASCT's investigative status: the procedure has not been approved by the FDA for market, and it remains in clinical trials. Even the third factor, regarding whether there are "medically reasonable conclusions establishing its safety, effectiveness, or effect on health outcomes," is negated by the MPM II-121. Id. at 105. Blue Cross did not act contrary to the clear language of the Plan - as required by the fifth prong of Finley - and instead followed the overwhelming weight of the "investigative" factors.

Blue Cross was not obligated to defer to Dr. Burt's conclusions about ASCT as applied to Wenzel. That is particularly true given the holistic approach required by the Plan's definition and the consensus of substantial evidence regarding the three factors. The fact that Dr. Burt believed that Wenzel was a prime candidate for treatment does not override all other evidence before the medical director. Further, the MPM II-121's analysis comports with and is supported by the language of the Plan. It was not an abuse of discretion for Blue Cross to reasonably conclude, based on

substantial evidence, that ASCT was investigative and to deny coverage for Wenzel on that basis.

2. Reasonableness of "Investigative" Classification for Comparable Efficacy of ASCT

Wenzel next contends that Blue Cross essentially added language to the Plan by requiring that ASCT be more effective than other treatments in order to receive coverage. This contention relies on multiple comments made by reviewers that are variations on the theme of "[further] trials are needed to determine whether [ASCT] improves outcomes when compared with conventional therapies." See, e.g., Admin. R. at 756.

The Plan requires Blue Cross to take a holistic look to determine whether experts can draw conclusions about a procedure's efficacy and safety. Wenzel concedes that the treatment is neither approved for marketing nor past the clinical trial stages of testing. Moreover, multiple peer-reviewed articles note that long-term, large-sample studies are required to confirm ASCT's safety and effectively measure ASCT's success in treating patients with MS. Blue Cross has not inserted language requiring that ASCT be more effective than traditional therapies, only that it be proven effective and not "investigative" under the Plan's definition.

Further, Blue Cross met its fiduciary duties by denying the request for an investigative procedure. Blue Cross has a fiduciary duty to all participants under the Plan. Barnhart v. UNUM Life

Ins. Co. of Am., 179 F.3d 583, 589 (8th Cir. 1999). The Plan's goal is to promote the health of all covered persons through payment of medical benefits, and the Plan maximizes those benefits by excluding payment for investigative procedures. Tillery, 280 F.3d at 1199-1200. To cover Wenzel's investigative procedure, which is not a covered benefit, would defeat the Plan's goal of providing benefits to other participants who were properly deserving of coverage. Cash v. Wal-Mart Grp. Health Plan, 107 F.3d 637, 643 (8th Cir. 1997); Phillips v. Kennedy, 542 F.2d 52, 55 n.8 (8th Cir. 1976). Such a result frustrates the first factor set forth in Finley, namely, to further the goals of the Plan. The court finds Blue Cross' interpretation of the Plan and subsequent classification of Wenzel's ASCT treatment as "investigative" was reasonable.[1]

3. Consistent Interpretation of the Plan

Wenzel argues that Blue Cross has inconsistently interpreted the term "investigative" as applied to ASCT for MS patients. Specifically, Wenzel points to redacted letters from Blue Cross Blue Shield of Illinois and Blue Cross Blue Shield of Utah, wherein the administrators of other plans approved the coverage of ASCT for

[1] Wenzel makes similar arguments regarding the other stages of his appeal. At each stage, the reviewers received both the MPM II-121 and Wenzel's own files. At each stage, the reviewers concluded that the ASCT procedure was investigative. The court finds that these conclusions were reasonable given the evidence before them.

MS patients.

"The plan, in short, is at the center of ERISA." US Airways, Inc. v. McCutchen, 133 S. Ct. 1537, 1548 (2013). Neither Blue Cross Blue Shield of Illinois nor Blue Cross Blue Shield of Utah are the same entity as Blue Cross Blue Shield of Minnesota. Wenzel provides no language from the other plans to evidence that they are the same as the Plan in this case. Indeed, a review of case law reveals that other Blue Cross entities use significantly different plan language and structure to determine coverage of investigative procedures. See, e.g., Kekis v. Blue Cross & Blue Shield of Utica Watertown, Inc., 815 F. Supp. 571, 579 (N.D.N.Y. 1993); Schnitker v. Blue Cross/Blue Shield of Neb., 787 F. Supp. 903, 904 (D. Neb. 1991); see also Robertson v. Blue Cross & Blue Shield of Tex., No. CV 14-224-M-DWM, 2015 WL 1715072, at *6 (D. Mont. Apr. 15, 2015), aff'd sub nom. Robertson v. Blue Cross, 612 F. App'x 478 (9th Cir. 2015). Without evidence to show that the same entity interpreting the same plan has come to different conclusions, Wenzel has failed to show inconsistent interpretation of the Plan by Blue Cross.

4. Medical Policy Manual as Applied to a Self-Insured Plan

Wenzel argues that Blue Cross should be barred from relying on the MPM II-121 at all because it is a subsection of the Medical Policy Manual (Manual), which applies "generally to all Blue Cross and Blue Plus fully insured plans and products." See Pl.'s Reply

Mem. at 2 (quoting Blue Cross' website). Wenzel claims that such language prohibits Blue Cross from applying the Manual to anything other than fully insured plans.

However, just two sentences after the statement quoted by Wenzel, Blue Cross explains that "Medicaid products may have additional policies and prior authorization requirements, as well as some self-insured plans." Id. Thus, (1) the Manual applies to both fully-insured and self-insured plans, and (2) some self-insured plans may have additional policies not included in the Manual. Wenzel's reading of the language does not acknowledge the word "additional" in the second sentence and is inconsistent with the plain language of the Manual. Blue Cross' reading embraces the meaning of both sentences and does not render any language of the Plan meaningless or internally inconsistent, as required by Finley.

Even if the court were to adopt Wenzel's reading, the Plan nevertheless provides, "If necessary, Blue Cross may utilize guidelines established by the [MPC], or other external resources." Admin. R. at 707. The Plan "expressly adopts and endorses" those guidelines. Id. Thus, Blue Cross can refer to the MPM II-121 under this provision, so long as it is necessary to the interpretation of the Plan. Wenzel argues that such reference was unnecessary because the Plan adequately described "investigative" for the purpose of application to Wenzel's treatment. However, the disagreement over ASCT's status supports the need to consult

external resources. The court finds that it was reasonable for Blue Cross to reference the MPM II-121 to assist in its interpretation of the Plan.

III. Procedural Errors

Wenzel also argues that Blue Cross committed several procedural errors in the composition of the MPC and in reviewing Wenzel's claim.

1. MPC Composition Error

Wenzel argues that Blue Cross violated the Plan because the MPC was not composed of "independent community physicians who represent a variety of medical specialties." Admin. R. at 30. However, Wenzel fails to name a single member of the MPC. Wenzel asserts that the Coverage Committee was composed of Blue Cross employees. But the Coverage Committee is not the MPC, and the Plan does not require that it be composed of independent community physicians. As a result, Wenzel has failed to meet his burden on this aspect of his claim.

2. Reasonableness of Review Procedure

Finally, Wenzel argues that the procedures for claim review were contrary to the Plan's language because Blue Cross failed to provide each reviewer with a copy of the Plan's definition of "investigative. The Plan has no such requirement, however. See id. at 37. Nevertheless, Blue Cross' denial letters to Wenzel specifically reference the Plan and the exclusion for investigative

procedures. Id. at 338, 248, 128. The Plan's language regarding exclusion of investigative procedures was also provided to the independent external medical reviewer AMR. Id. at 555-56.

Wenzel's complaint argues that he is entitled to coverage and seeks reimbursement for the benefits denied to him under the Plan. Compl. ¶ 36. The court finds that Blue Cross did not abuse its discretion when it acted reasonably, based on substantial evidence, in denying Wenzel's request for coverage.

CONCLUSION

Accordingly, based on the above, IT IS HEREBY ORDERED that:

1. Defendant's motion for summary judgment [ECF No. 12] is granted; and

2. Plaintiff's motion for summary judgment [ECF No. 16] is denied.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: October 28, 2015

s/David S. Doty
David S. Doty, Judge
United States District Court